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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/724,726	Applicant(s) HADLACZKY ET AL.	
	Examiner BRENT PAGE	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-52, 73-79, 81, 84, 87-95, 97-99, 101, 104, 108, 111, 114, 115, 117, 119-121 and 128 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 50-52,73-79,81,84,87-95,97-99,101,104,108,111,114,115,117,119-121 and 128.

DETAILED ACTION

The Reply filed by Applicant on 06/23/2009 and the supplemental Reply filed on 07/08/2009 are both hereby acknowledged. Claims 50-52,73-79,81,84,87-95,97-99,101,104,108,111,114,115,117,119-121 and 128 are pending and examined herein on the merits.

Preliminary Arguments

Regarding in vitro assembly of SATACs

Applicants urge that it is clear by the description in specification that SATACs provide source material for the assembly of artificial chromosomes and are not in themselves *in vitro* constructed chromosomes (see pages 6-9 of response).

This is not persuasive because none of the arguments nor statements in the specification define a SATAC as having to be formed in the way exemplified in the specification in mammalian cells. The definition of the SATAC is instead, a recitation of DNA elements, which do not specify how each element is arrived at. It is suggested that if Applicant wished to define a SATAC as a chromosome only formed from existing chromosomes and formed only within a cell, that such language should have been included in the definition of the term.

Applicants urge that no knowledge of the centromere sequence is necessary for the formation of SATACs in a plant cell (see pages 9-12).

This is not persuasive for the reasons of record presented in the previous office actions. This is further not persuasive, because such identification is required to 1) identify that one has possession of a SATAC since a SATAC by definition must have a

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functioning centromere and 2) the exemplified embodiments use such a feature, and guidance is not adequately provided for plant cells without using such a sequence.

Applicants urge that DECLARATIONS of record provide evidence of the formation of SATACS in plants and that stable maintenance of the SATACs are evidence of centromere function (see pages 12-14 of response).

This is not persuasive because the exemplified mammalian SATACs used methods identifying the centromere on the basis of sequence and/or antibody to show a functioning centromere. The DECLARATIONS provided do not follow the methods exactly as taught in the specification and do not demonstrate centromere formation as taught in the specification.

Claim Rejections - 35 USC § 112-enablement

Claims 50-52,73-79,81,84,87-95,97-99,101,104,108,111,114,115,117,119-121 and 128 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims remain rejected for the reasons presented in the office actions mailed out on 01/17/2003, 10/22/2003, 08/12/2004, 05/09/2005, 03/30/2006, 07/31/2007, 05/13/2008, 12/23/2008, as well as the reasons set forth below.

Applicant's arguments filed 06/23/2009 and 07/08/2009 have been fully considered but they are not persuasive.

Applicant urges that cytological and FISH methods were well known to one of skill in the art at the time of filing as applicable to plants, and assert that it is unclear why the Examiner concludes that such techniques do not work in plants (see pages 14-19 of response).

This is not persuasive because the state of the art does not support Applicants assertion that the methods and techniques available for cytological techniques were readily applicable to plant cells at the time of filing. This is not supported by the references provided by Applicant, and in fact, these references evidence the differences in the state of the art between mammalian and plant cells. For example, Leitch et al state "However, the technique for gene mapping in plants has lagged behind that for animal chromosome mapping probably as a result of problems associated with the plant cell wall and cytoplasmic material" (see page 329, 2nd paragraph) and "Comparing hybridization sites of different probe on different metaphase chromosomes is unsatisfactory because measurements between probe site and morphological features of chromosomes (including telomeres, centromeres, and nuclear organizing regions) will differ depending on chromosome condensation and other factors" (see page 331 1st paragraph under discussion). Jiang et al state that variability among plant species is expected and state "The successful application of this technique in other plant species will depend on both the size of the genomic clones analyzed and the percentage of repetitive DNA sequences in the genome" (see page 4490 1st paragraph under

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Discussion) two factors not addressed by the current application. Murata et al state "However, almost no signals were detected in any chromosomes of the mitotic metaphase cells (Table 2)" (see page 40 1st paragraph under Efficiency of detection of hybridization signals) and "In the present study, we localized genomic DNA sequences greater than 11kb in size on Arabidopsis chromosomes. This could only be reliably achieved using the floral tissues" and "The discrepancy in efficiency of hybridization between root and floral chromosomal preparations might be caused by the difference in chromatin structure between the two tissues" (see page 42 1st full paragraph). It is asserted by the Examiner that the references cited by Applicant actually demonstrate the large diversity and number of problems between species and probe types as unpredictability associated with identifying chromosomal amplification in the large diversity of plant species, tissues and chromosomes as broadly claimed.

Applicants urge that the specification provides extensive guidance and teachings for introducing a SATAC into a plant cell (see pages 14-15 of response).

This is not persuasive because as discussed in great detail previously, the state of the art regarding mammalian chromosomes and plant chromosomes and the materials and methods for identification were very different at the time of filing. One of skill in the art would not have been enabled to practice the invention on plant cells using only the guidance provided in the specification, guidance geared specifically for mammalian cells. A DECLARATION may not provide the enabling guidance in place of the specification.

Applicants urge that the DECLARATIONS of record demonstrates that one of skill in the art may introduce SATACs into plant cells using methods taught in the specification (see pages 18-20 of response, and DECLARATION).

This is not persuasive because absent evidence to the contrary, plant cell fusion with mammalian cells was not routine in the art, and guidance was not present in the specification that would have enabled one of skill in the art to do so. Details provided in the DECLARATION (such as the ratio of 10:1 microcells to protoplasts) may not be treated as mere optimization when such methods are wholly unknown in the prior art.

Applicants urge that the specification does not teach that centromeric sequences are required to identify SATACs, and that working examples while identifying the centromere, do not maintain that such identification is required (see pages 20-21).

This is not persuasive because initially, to show the successful production of SATACs in mammalian cells, the identification of centromeric sequences were used. Contrary to Applicants assertions, the bar for enablement would be at least as high for demonstrating such generation in plants. Applicants have defined the SATAC as a chromosome that must have a functioning centromere. Applicants have not provided guidance in the specification for identifying that structure in plants.

Applicants urge that the Examiner's statements regarding acentric chromosome tethering is inappropriate and fanciful (see pages 21-22 of response).

This is not persuasive because the cited art was used to both demonstrate the state of the art regarding plant chromosomes and the differences between plant cells and animal cells regarding chromosome stability. The Examiner did not contend that

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the Declaration contained tethered acentric chromosomes, but was merely pointing out the importance of centromeric sequences in establishing that a SATAC has been formed.

Applicants urge that the presently claimed method is universal and that it is “unequivocally clear” that the specification describes and teaches a universal process that works equally in plants and animals (See pages 23-25 of response).

This is not persuasive because there is no data, no demonstration, and no teaching taking into account the differences in chromosome structure between plants and animals to indicate that the method had successfully been practiced in plants, or to enable one to apply the taught method to plants since differences in techniques, probes and materials and methods notably in the DECLARATIONS of record as discussed in previous office actions evidence that the methods taught are not universal using the same materials taught in the specification. The state of the art does not provide such details or modifications, and thus undue experimentation would be required to practice the method with plant cells.

Applicants arguments on pages 30-33 are duplicative and summed up in the statement “The Examiner has provided no reasoning or scientific basis why any of these methods would not work in plants” (see pages 26-28).

This is not persuasive because the state of the art, the unpredictability and the multitude of difference between plants and animal chromosomes and chromosome technology have been cited in the previous office actions as well as above.

Claim Rejections - 35 USC § 112-written description

Claims 50-52,73-79,81,84,87-95,97-99,101,104,108,111,114,115,117,119-121 and 128 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims remain rejected for the reasons presented in the office actions mailed out on 01/17/2003, 10/22/2003, 08/12/2004, 05/09/2005, 03/30/2006, 07/31/2007, 05/13/2008, 12/23/2008, as well as the reasons set forth below.

Applicant's arguments filed 06/23/2009 and 07/08/2009 have been fully considered but they are not persuasive.

Applicants urge that working examples are not required for every claimed embodiment and that the methods instantly claimed are universal (see pages 28-32 of response).

This is not persuasive because where working examples are not provided either the state of the art must be of a level that provides adequate description for the further embodiments, or the specification must describe the structure-function relationship of the claimed subject matter that demonstrates possession of the claimed subject matter. As discussed in great detail in previous office actions and above, the state of the art between plant chromosomes and animal chromosomes was very different at the time of

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filing and so does not provide the details necessary to show possession. As discussed in previous office actions the details provided in the specification showing generation of mammalian SATACs are not applicable to plants since plants do not contain alpha-satellite DNA and have a different composition. Furthermore, the many tools, in the form of probes, and antibodies were not readily available for similarly screening plant cells at the time of filing.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Anne Marie Grunberg/

Supervisory Patent Examiner, Art Unit 1638